IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EISAI CO., LTD., EISAI INC. and NOVARTIS PHARMA AG,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Eisai Co., Ltd. and Eisai Inc. (collectively, "Eisai") and Novartis Pharma AG ("Novartis") (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Pharma") (collectively, "Lupin"), hereby allege as follows:

THE PARTIES

1. Plaintiff Eisai Co., Ltd. is a Japanese corporation having a principal place of business at 6-10 Koishikawa 4-chrome, Bunkyo-ku, Tokyo 112-8088, Japan.

2. Plaintiff Eisai Inc. is a Delaware corporation having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

3. Plaintiff Novartis is a Swiss corporation having a principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Upon information and belief, Defendant Lupin Ltd. is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Defendant Lupin

Ltd., itself and through its wholly owned subsidiary and agent Lupin Pharma, sells various drug products in the United States, including in this judicial district.

5. Upon information and belief, Defendant Lupin Pharma is a Virginia corporation and wholly owned subsidiary and agent of Defendant Lupin Ltd., having a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief Defendant Lupin Pharma sells various drug products in the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action concerning the infringement of United States Patent Nos. 6,740,669 ("the '669 patent"), 7,750,028 ("the '028 patent") and 8,076,362 ("the '362 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over both Lupin Ltd. and Lupin Pharma by virtue of, *inter alia*, the fact that they have committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Eisai Inc., a Delaware corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. This Court has personal jurisdiction over both Lupin Ltd. and Lupin Pharma because they have previously been sued in this district and have not challenged personal jurisdiction, and they have affirmatively availed themselves of the jurisdiction of this Court by

filing counterclaims in this district. *See, e.g., Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., and PF Prism C.V. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, 12-cv-00811; *Novartis Pharmaceuticals Corporation v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, 12-cv-00595; *Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd., and Allegan, Inc. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, 11-cv-00271.

10. Upon information and belief, Lupin has received more than 75 approvals from the FDA for drug products, such as "Suprax®," and sells drug products throughout the United States, including this judicial district.

11. Upon information and belief, Lupin entered into a multi-year contract with Forest Laboratories, Inc., a Delaware corporation, to promote the "AeroChamber Plus®" product. Upon information and belief, Lupin distributes the "AeroChamber Plus®" product for sale throughout the United States, including in this judicial district.

12. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, the fact that they availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware, and have appointed a registered agent for service of process in Delaware.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PATENTS-IN-SUIT

14. On May 25, 2004, the '669 patent, titled "Crystal Modification of 1-(2, 6-Difluorobenzyl)-1H-1, 2, 3-Triazole-4-Carboxamide and its Use as Antiepileptic," was issued. A copy of the '669 patent is attached as Exhibit A.

15. On July 6, 2010, the '028 patent, titled "Crystal Modifications of 1-(2, 6-Difluorobenzyl)-1H-1, 2, 3-Triazole-4-Carboxamide," was issued. A copy of the '028 patent is attached as Exhibit B.

16. On December 13, 2011, the '362 patent, titled "Crystal Modification A of 1-(2, 6-Difluorobenzyl)-1H-1, 2, 3-Triazole-4-Carboxamide and Dosage Forms and Formulations Thereof," was issued. A copy of the '362 patent is attached as Exhibit C.

ACTS GIVING RISE TO THIS ACTION

17. Eisai holds New Drug Application ("NDA") No. 21-911 for oral tablets containing 200 or 400 mg of the active pharmaceutical ingredient rufinamide. Eisai markets and sells these tablets in the United States under the brand name "Banzel®."

18. Novartis owns the patents-in-suit. Eisai holds an exclusive license to the patents-in-suit in the United States.

19. Pursuant to 21 U.S.C. § 355(b)(1), the '669, '028 and '362 patents are listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Banzel® or its use.

20. Upon information and belief, Lupin submitted ANDA No. 204964 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Lupin's ANDA No. 204964 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 100, 200 and 400 mg of rufinamide ("the Lupin Generic Product") prior to the expiration of the '669, '028 and '362 patents.

21. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Lupin certified in ANDA No. 204964 that the claims of

the '669, '028 and '362 patents are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Lupin Generic Product.

22. Plaintiffs received written notification of Lupin's ANDA No. 204964 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated June 13, 2013 ("Notice Letter").

23. This action was commenced within 45 days of the Lupin Notice Letter.

FIRST COUNT
INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 6,740,669

24. Plaintiffs re-allege paragraphs 1-23 as if fully set forth herein.

25. In its Notice Letter, Lupin did not allege noninfringement of Claims 1-21 of the '669 patent separate and apart from any assertions regarding the validity of those claims.

26. Lupin's submission of ANDA No. 204964 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '669 patent under 35 U.S.C. § 271(e)(2)(A).

27. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Lupin Generic Product, if approved by the FDA, prior to the expiration of the '669 patent including its patent term extension, would infringe the '669 patent under 35 U.S.C. § 271.

28. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Lupin's ANDA No. 204964 be a date that is not earlier than the expiration of the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '669 patent to which Plaintiffs are or become entitled.

29. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

30. Upon information and belief, Lupin was aware of the existence of the '669 patent and was aware that the filing of its ANDA and certification with respect to the '669 patent constituted an act of infringement of that patent.

SECOND COUNT
INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 7,750,028

31. Plaintiffs re-allege paragraphs 1-30 as if fully set forth herein.

32. In its Notice Letter, Lupin did not allege noninfringement of Claims 1-8 of the '028 patent separate and apart from any assertions regarding the validity of those claims.

33. Lupin's submission of ANDA No. 204964 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Lupin Generic Product, if approved by the FDA, prior to the expiration of the '028 patent including its patent term extension, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '028 patent. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Lupin's ANDA No. 204964 be a date that is not earlier than the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '028 patent to which Plaintiffs are or become entitled.

35. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

36. Upon information and belief, Lupin was aware of the existence of the '028 patent and was aware that the filing of its ANDA and certification with respect to the '028 patent constituted an act of infringement of that patent.

THIRD COUNT
INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 8,076,362

37. Plaintiffs re-allege paragraphs 1-36 as if fully set forth herein.

38. In its Notice Letter, Lupin did not allege noninfringement of Claims 1-21 of the '362 patent separate and apart from any assertions regarding the validity of those claims.

39. Lupin's submission of ANDA No. 204964 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '362 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Lupin Generic Product, if approved by the FDA, prior to the expiration of the '362 patent, would infringe the '362 patent under 35 U.S.C. § 271. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Lupin's ANDA No. 204964 be a date that is not earlier than the expiration of the '362 patent, or any later expiration of exclusivity for the '362 patent to which Plaintiffs are or become entitled.

41. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

42. Upon information and belief, Lupin was aware of the existence of the '362 patent and was aware that the filing of its ANDA and certification with respect to the '362 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Lupin has infringed one or more claims of the '669 patent;

B. Lupin has infringed one or more claims of the '028 patent;

C. Lupin has infringed one or more claims of the '362 patent;

D. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Lupin's ANDA No. 204964 shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

E. That Lupin, its officers, agents, servants and employees, and those persons acting in concert, participation, or in privity with any of them, and their successors or assigns, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing into the United States the Lupin Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '669, '028, or '362 patent prior their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

F. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur in prosecuting this action; and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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July 24, 2013